Torsion Strength of Biodegradable and Titanium Screws: A Comparison

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Purpose: To determine *1*) the differences in maximum torque between 7 biodegradable and 2 titanium screw systems, and *2*) the differences of maximum torque between "hand tight" and break of the biodegradable and the titanium osteofixation screw systems.

Materials and Methods: Four oral and maxillofacial surgeons inserted 8 specimens of all 9 screw systems in polymethylmethacrylate plates. The surgeons were instructed to insert the screws as they would do in the clinic (hand tight). The data were recorded by a torque measurement meter. A PhD resident inserted 8 specimens of the same set of 9 screw systems until fracture occurred. Likewise, the maximum applied torque was recorded.

Results: *1*) The mean maximum torque of the 2 titanium screw systems was significantly higher than that of the 7 biodegradable screw systems, and *2*) the mean maximum torque for hand tight was significantly lower than for break in 2 biodegradable, and both titanium screw systems.

Conclusions: Based on the results, we conclude that the 1.5 mm and 2.0 mm titanium screw systems still present the highest torque strength compared with the biodegradable screw systems. When there is an intention to use biodegradable screws, we recommend the use of 2.0 mm BioSorb FX (Linvatec Biomaterials Ltd, Tampere, Finland), 2.0 mm LactoSorb (Walter Lorenz Surgical Inc, Jacksonville, FL), or the larger 2.5 mm Inion (Inion Ltd, Tampere, Finland) screws.

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Fast, anatomical, and pain-free reunion of bone fragments are the essential goals in orthognathic and trauma surgery.[1] Adequate reposition, stabilization, and fixation of fractured or osteotomized bone segments are essential preconditions.[2,3] Plates and screws are generally used for the internal stabilization and fixation of the bone segments.[4,5] Screws are used to fix osteofixation plates or to position bone segments (eg, sagittal split osteotomies).[6] During insertion, the screws occasionally break.[7] Fracture of a screw occurs when the applied torque is higher than the maximum allowable torque of the screw. Removal of broken screws and reapplication of screws is expensive and time-consuming. Besides, additional operations may result in complications and subsequent compromised bone healing.

It is generally acknowledged that biodegradable screws have different torsion characteristics than titanium screws. Some clinical studies reported a higher number of broken biodegradable screws compared with titanium screws.[7,8] Several authors have reported this experience as a considerable disadvantage.[9-11] The maximum torque strength differs for the various screws mainly because of the use of different materi-

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Table 1. CHARACTERISTICS OF INCLUDED OSTEOFIXATION SCREWS

Brand Name	Manufacturer (Location)	Composition	Sterility	Screw Diameter*	Screw Length*
Biodegradable screws					
BioSorb FX	Linvatec Biomaterials Ltd (Tampere, Finland)	SR 70L/30DL PLA	Sterile	2.0 mm	6.0 mm
Resorb X	Gebrüder Martin GmbH & Co (Tuttlingen, Germany)	100 DL-Lactide	Sterile	2.1 mm	7.0 mm
Inion 2.0	Inion Ltd (Tampere, Finland)	LDL Lactide/TMC†	Sterile	2.0 mm	7.0 mm
Inion 2.5	Inion Ltd (Tampere, Finland)	LDL Lactide/TMC†	Sterile	2.5 mm	7.0 mm
LactoSorb	Walter Lorenz Surgical Inc (Jacksonville, FL)	82 PLLA/18 PGA	Sterile	2.0 mm	7.0 mm
Polymax	Mathys Medical Ltd (Bettlach, Switzerland)	70L/30DL PLA	Sterile	2.0 mm	6.0 mm
MacroPore	MacroPore BioSurgery Inc (Memphis, TN)	70L/30DL PLA	Expired	2.0 mm	6.0 mm
Titanium screws					
KLS Martin	Gebrüder Martin GmbH & Co (Tuttlingen, Germany)	Titanium (pure)	Sterile	1.5 mm	6.0 mm
KLS Martin	Gebrüder Martin GmbH & Co (Tuttlingen, Germany)	Titanium (pure)	Sterile	2.0 mm	6.0 mm

Abbreviations: SR, self-reinforced; TMC, trimethylene-carbonate; PGA, polyglycolic acid; PLA, polylactic acid; PLLA, poly-L-lactic acid.
*According to specifications of the manufacturers.
†Polymer composition not specified by the manufacturer.

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als for manufacturing (biodegradable) screws, and different geometry of those screws.

The manufacturers do not specify the torque for inserting the screws. The torque to be applied for adequate tightening the screws can be defined as "hand tight." The maximally applied torque is, to some extent, controlled by the construction of the screwdriver handles (diameter, hand posture, geometry, and texture). But with most handles, the maximum torque that can be applied exceeds the torque strength of the screws, so fracture of the screws might occur. An estimate of a safe torque for screws of different diameter and length is difficult, especially for biodegradable screws.[12] Moreover, many surgeons are not that experienced in using polymeric screws. To guide decisions regarding the selection and application of different osteofixation screws, clarification of the differences in torque strength of biodegradable as well as titanium osteofixation screw systems could be valuable.[13]

Objectives

The objectives of this study were to determine *1*) the differences in maximum torque between 7 biodegradable and 2 titanium screw systems, and *2*) the differences in maximum torque between hand tight and break of the biodegradable as well as the titanium screw systems.

Materials and Methods

Seven (5 × 2.0 mm, 1 × 2.1 mm, and 1 × 2.5 mm) commercially available biodegradable as well as 2 (1.5 mm and 2.0 mm) commercially available titanium screw systems were investigated. The biodegradable and titanium implants were gratuitously supplied by the manufacturers. The manufacturers, with 1 exception (MacroPore BioSurgery Inc, Memphis, TN), supplied sterile implants. The MacroPore implants exceeded the expiration date by 6 to 12 months. Nevertheless, we decided to include these implants in the tests. The general characteristics of the investigated screw systems are summarized in Table 1.

Four oral and maxillofacial surgeons were requested to insert 8 specimens of all 9 screw systems in polymethylmethacrylate plates. The holes were predrilled for both the titanium and the biodegradable screws, and subsequently pretapped (as prescribed) for the biodegradable screws according to the prescriptions of the individual manufacturers (with prescribed burs and taps). The surgeons were instructed to insert the screws as they would do in the clinic (hand tight). A PhD resident inserted 8 specimens of the same set of 9 screw systems until fracture occurred. The screws were inserted at room temperature, as this is the regular operating room temperature. Before insertion of the screws, the holes were irrigated with physiological fluid to simulate the in situ lubrication. The maximally applied torque was

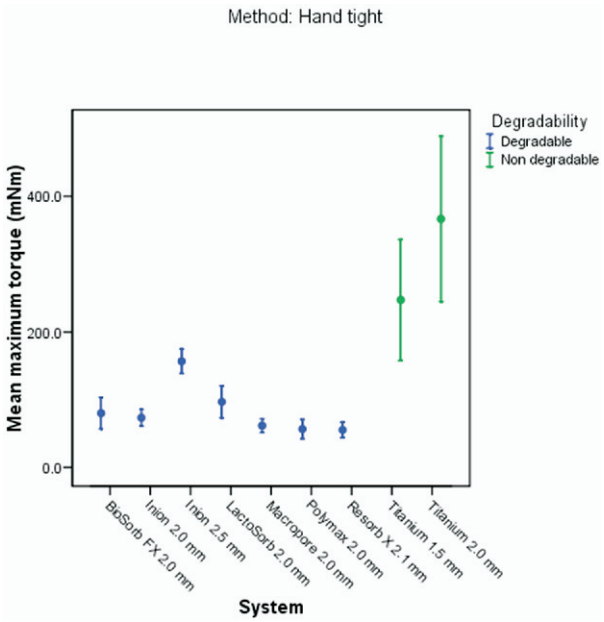

FIGURE 1. Mean maximum torque for method hand tight, organized by screw system. Brand names of the investigated osteofixation systems are shown on the x-axis (manufacturer information according to Table 1), and maximum torque measured (mNm) during insertion is shown on the y-axis. Points in figure represent mean maximum torque for degradable (*blue*) and nondegradable (*green*) systems, and *bars* represent the standard deviation of the mean maximum torque.

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recorded by a torque measurement meter (Nemesis Howards Torque Gauge, Smart MT-TH 50 sensor; accuracy 2.5 mNm, range 0-500 mNm; supplied by Hartech, Wormerveer, The Netherlands).

STATISTICAL ANALYSIS

The data were analyzed using the Statistical Package of Social Sciences (SPSS, Chicago, IL), version 14.0. Descriptive statistics were used to calculate means and standard deviation. The measured maximum torque of the 32 different specimens (8 specimens × 4 surgeons) of each screw system were averaged. To determine whether there were significant differences between the biodegradable and the titanium osteofixation screw systems, the mean maximum torques were subjected to an ANOVA. A correction for multiple testing was performed according to Dunnet T3 (equal variances not assumed). The differences between maximum torque of hand tight and break of the various screw systems were statistically compared with Student *t* tests. Differences were considered to be significant when *P* was less than .05 for all tests.

Results

The mean maximum torque and standard deviation of the 9 osteofixation screws systems for hand tight are graphically plotted in Figure 1. The mean maximum torque of the biodegradable systems was significantly lower compared with the mean maximum torque of both titanium systems (Table 2). The standard deviations of the titanium screw systems were considerable larger than those of the biodegradable screw systems. Figure 2 shows the mean maximum torque of the 9 osteofixation screw systems at break. The standard deviations of the titanium systems, shown in Figure 2, were lower than those of the biodegradable systems, especially when compared with the results shown in Figure 1. The plot of the 2.0-mm titanium screw system did not show a standard deviation because the torque for breaking the screws exceeded the maximum limit of the torque measurement apparatus. The mean maximum torque was set at 680 mNm (as measured by the torque measurement apparatus, however not with the accuracy of 2.5 mNm). The mean maxi-

Table 2. STATISTICAL DIFFERENCES BETWEEN OSTEOFIXATION SCREWS

System*	BioSorb FX 2.0 mm	Inion 2.0 mm	Inion 2.5 mm	LactoSorb 2.0 mm	Macropore 2.0 mm	Polymax 2.0 mm	Resorb X 2.1 mm	Titanium 1.5 mm	Titanium 2.0 mm
BioSorb FX 2.0 mm	**NS**	S	NS	NS	S	S	S	S	S
Inion 2.0 mm	*NS*	**NS**	S	S	NS	NS	NS	S	S
Inion 2.5 mm	*S*	*S*	**S**	NS	S	S	S	S	S
LactoSorb 2.0 mm	*NS*	*S*	*S*	**S**	S	S	S	S	S
Macropore 2.0 mm	*S*	*S*	*S*	*S*	**NS**	NS	NS	S	S
Polymax 2.0 mm	*S*	*S*	*S*	*S*	*NS*	**NS**	NS	S	S
Resorb X 2.1 mm	*S*	*S*	*S*	*S*	*NS*	*NS*	**NS**	S	S
Titanium 1.5 mm	*S*	*S*	*S*	*S*	*S*	*S*	*S*	**S**	S
Titanium 2.0 mm	*S*	*S*	*S*	*S*	*S*	*S*	*S*	*S*	**S**

NOTE. Hand tight method shown in *italic* and break method shown in *underlined* text. On the diagonal, and shown in *bold* text, are results of comparisons of hand tight versus break methods.

Abbreviations: NS, not significant; S, significant.

*Manufacturer information according to Table 1.

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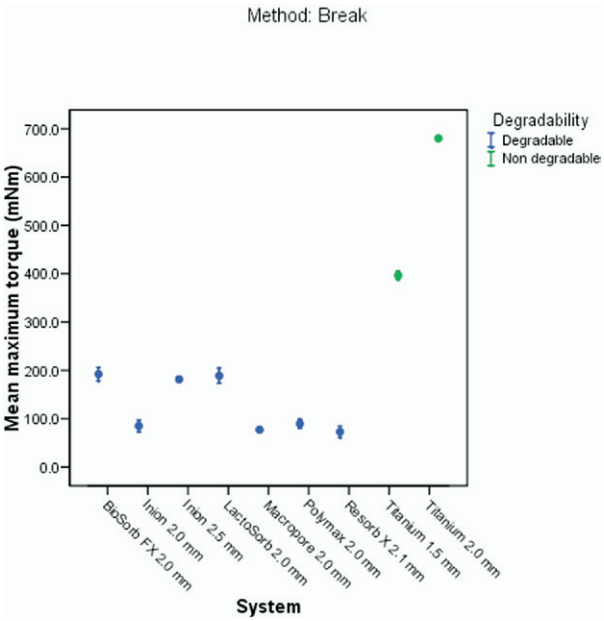

FIGURE 2. Mean maximum torque regarding method break, organized by screw system. Brand names of the investigated osteofixation systems are shown on the x-axis (manufacturer information according to Table 1), and maximum torque measured (mNm) during insertion is shown on the y-axis. Points in figure represent mean maximum torque for degradable (*blue*) and nondegradable (*green*) systems, and *bars* represent the standard deviation of the mean maximum torque.

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mum torque of both titanium screw systems was significantly higher than the 7 different biodegradable screw systems. With respect to the 7 biodegradable screw systems, the Inion 2.5 screw system represented a significantly higher torque than the other biodegradable systems for the method hand tight. Regarding the break method, the mean maximum torque of the BioSorb FX, Inion 2.5, and LactoSorb screw systems was significantly higher than the 4 remaining biodegradable screw systems. Different comparisons regarding significant differences of the various screw systems for hand tight and break are outlined in Table 2.

Figure 3 shows the mean maximum torque of the screw systems organized by surgeon and screw system. The surgeons showed a wider distribution of the mean maximum torque of the titanium screw systems compared with the biodegradable screw systems. This corresponds to the large standard deviations for hand tight presented in Figure 1.

Table 3 presents a summary of the descriptive statistics. The mean, standard deviation, 95% confidence interval, and the range are presented and organized by method. Table 3 shows for each screw system, the mean maximum torque at break to be above the mean maximum torque at hand tight. A statistical comparison of the mean maximum torque of hand tight and break for LactoSorb, Inion 2.5, titanium 1.5 mm, and titanium 2.0 mm screw systems showed that the mean maximum torques for break were significantly higher than the mean maximum torque for hand tight (diagonal of Table 2).

Discussion

The differences in maximum torque found for the studied systems can be explained by the different screw diameters (1.5, 2.0, 2.1, and 2.5 mm), different (copolymer) compositions, different geometry (pitch and shaft) of the screws, different tools used to insert the screws, different ages of the screws, and different methods to sterilize the screws. As expected, the use of titanium for manufacturing osteofixation screws revealed a high maximum torque strength whereas the use of polymers revealed a significantly lower torque strength. A surprising finding was the significant mean maximum torque difference of the BioSorb FX, Inion 2.5, and LactoSorb screw systems compared with the remaining 4 biodegradable screw systems for the method break. The self-reinforced polymers of the BioSorb FX screw system, the larger dimensions of the 2.5 mm Inion screws, and the ponderous geometry of the LactoSorb screws are probably responsible for the high maximum torque. The large standard deviations of the 2 titanium screw systems presented

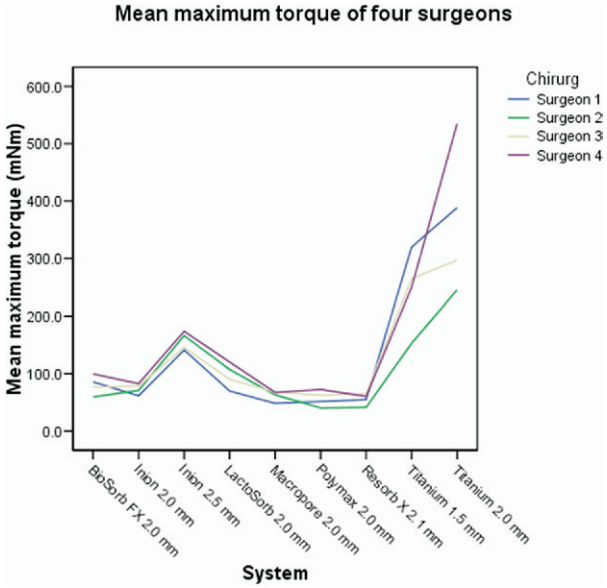

FIGURE 3. Mean maximum torque of the 4 surgeons who inserted the screws, organized by screw system and surgeon. Brand names of the investigated osteofixation systems are shown on the x-axis (manufacturer information according to Table 1), and maximum torque measured (mNm) during insertion is shown on the y-axis. Points in figure represent mean maximum torque for surgeon 1 (*blue*), surgeon 2 (*green*), surgeon 3 (*gray*), and surgeon 4 (*purple*),

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Table 3. SUMMARY OF DESCRIPTIVE STATISTICS

System*	Mean†	SD†	95% Confidence Interval		Range	
			Lower Bound†	Upper Bound†	Lowest Value†	Highest Value†
Hand tight method						
BioSorb FX 2.0 mm	80.23	23.41	69.64	90.81	38.10	132.40
Inion 2.0 mm	73.42	12.22	62.84	84.01	37.30	94.20
Inion 2.5 mm	156.85	17.98	146.27	167.44	105.00	182.5
LactoSorb 2.0 mm	96.90	23.51	86.31	107.48	62.80	139.30
Macropore 2.0 mm	61.60	10.23	51.06	72.23	35.70	83.40
Polymax 2.0 mm	56.70	14.30	46.08	67.26	30.10	89.30
Resorb X 2.1 mm	55.40	11.47	44.81	65.98	27.80	69.80
Titanium 1.5 mm	246.90	89.10	236.30	27.48	94.40	379.70
Titanium 2.0 mm	366.60	122.11	356.01	377.18	194.20	611.00
Break method						
BioSorb FX 2.0 mm	192.20	14.18	184.92	199.48	175.40	210.50
Inion 2.0 mm	85.08	12.29	77.79	92.36	63.00	104.20
Inion 2.5 mm	181.34	5.49	174.09	188.66	173.8	189.2
LactoSorb 2.0 mm	188.80	15.74	181.47	196.03	160.10	216.00
Macropore 2.0 mm	77.19	5.05	69.90	84.47	69.60	83.80
Polymax 2.0 mm	89.48	8.92	82.19	96.76	71.80	98.90
Resorb X 2.1 mm	72.86	11.85	65.58	80.15	58.00	96.80
Titanium 1.5 mm	396.48	9.01	389.19	403.76	388.20	416.30
Titanium 2.0 mm	680.00	0.00	672.72	687.28	680.00	680.00

*Manufacturer information according to Table 1.
†Data in mNm.

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in Figure 1 are probably caused by the higher maximum torque. After all, when surgeons apply higher torque forces, this inevitably implies loss of accuracy.

The comparison of the maximum torque of hand tight and break for the individual screw systems showed statistically significant differences for 4 (LactoSorb, Inion 2.5, titanium 1.5 mm, and titanium 2.0 mm) of the 9 osteofixation screw systems (diagonal in Table 2). In the case of individual biodegradable screws (Inion 2.0 mm, Inion 2.5 mm, MacroPore 2.0 mm, and Resorb × 2.1 mm), the lowest torque at break was not always above the highest torque of hand tight. Besides, the 95% confidence intervals of the maximum torque with respect to break and hand tight of biodegradable screws did overlap (Table 3). These 2 aspects indicate that the torsion characteristics of biodegradable screws are not always repeatable.

For analyzing the results, the data of the 4 surgeons have been combined in order to reduce the influence of outliers and to determine statistical significant differences. The results of the independent surgeons are graphically presented in Figure 3. Note the large differences in mean maximum torque for the 2 titanium systems compared with the 7 biodegradable systems. Statistical analysis yielded no significant differences between most surgeons except for 2 surgeons. This is largely due to the statistical influence of the large differences in mean maximum torque for titanium screws. Despite the significant difference between the 2 surgeons, the data were combined. After all, combining the results of the 4 surgeons should be allowed because the insertion torque of screws of maxillofacial surgeons should be approximately equal.

Investigating 7 different biodegradable screws theoretically implies 7 learning curves, as is the case with every new technique.[14-16] These learning curves could influence the results and consequent statistically significant differences. To find out whether the learning curves affected the results, the screw 1 and 2 data have been deleted for every surgeon and system. The raw data were then analyzed (6 instead of 8 screws) again. Eliminating the first 2 screws did not reveal statistically different (significant) results between the osteofixation screw systems.

Statistically significant differences do not necessarily imply differences to be clinically relevant. With respect to the investigated osteosynthesis screws in this study, it is questionable whether the statistically significant differences are clinically relevant. The large significant differences between titanium screws and biodegradable screws in mean maximum torque are clinically relevant, although the field of application may be different. In contrast, the statistically significant differences between some of the 7 biodegradable devices regarding the method hand tight are not clinically relevant, because they are considered to be too small. Moreover, it has been reported that biodegradable devices physically relax under constant

force (a process called creep). In this case, the applied torque is "counteracted" by the reorganizing polymer chains.[10] Titanium screws do not undergo this material relaxation. The significant differences between some of the 7 biodegradable devices for the method break are of clinical importance, because biodegradable screws can fracture easily during insertion. The significant differences of maximum torque for hand tight and break of 2 biodegradable (Inion 2.5, and LactoSorb) as well as both titanium screw systems presented in the current study are clinically relevant. After all, screws will break easily during insertion, when the differences between hand tight and break are small.

The objectives of this investigation were to determine *1*) the differences in mean maximum torque between 7 biodegradable and 2 titanium screw systems, and *2*) the differences of mean maximum torque between hand tight and break of the biodegradable as well as the titanium osteofixation screw systems. This study has shown that *1*) the mean maximum torque of titanium screw systems was significantly higher than of the biodegradable screw systems, and *2*) the mean maximum torque of all 9 screw systems at break was (significantly) higher than at hand tight. Based on the results and discussion points mentioned above, we can conclude that the 1.5 mm and 2.0 mm titanium screw systems still present the highest torque strength compared with the biodegradable screw systems. When there is an intention to use biodegradable screws, we would recommend the use of 2.0 mm BioSorb FX, 2.0 mm Lactosorb, or the larger 2.5 mm Inion screws.

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